UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,532	07/06/2001	Leonid Zhelnin	02973.00040	3386

22907 7590 02/25/2004

BANNER & WITCOFF
1001 G STREET N W
SUITE 1100
WASHINGTON, DC 20001

EXAMINER	
GUCKER, STEPHEN	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/899,532	ZHELNIN ET AL.	
	Examiner	Art Unit	
	Stephen Gucker	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *9-11,13-37 and 40-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,12,38 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/8/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group I, claims 1-8, 12, 38, and 39, filed 10/27/03, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 9-11, 13-37, and 40-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse as set forth above.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for these reason(s): FIG. 1 as described on page 8 of the specification requires the SEQ ID NOs for the sequences shown in FIG. 1. These SEQ ID NOs may appear either in the Brief Description of the Drawings section of the specification, or on the actual figures themselves.

3. Applicant should review the instant Application in its entirety for compliance with the sequence rules, paying particular attention that all sequences recited throughout the disclosure in its entirety have SEQ ID NOs and that the SEQ ID NOs recited are found in both the CRF and paper copy of the Sequence Listing. Applicant must comply with the sequence rules and the remainder of the entire Office action simultaneously. Otherwise, the applicant will receive a Notice of Non-Responsive Reply.

4. Applicant is given the shortened statutory period of THREE MONTHS from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period.

> The following is a quotation of the first paragraph of 35 U.S.C. 112:
>
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 38-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification adequately enables an expression vector for expressing the G-protein coupled receptor of the instant invention for the purposes of transfecting cells to make and isolate the receptor protein, making antibodies to the receptor protein, using the receptor protein in screening assays, etc. What the specification fails to enable is an expression vector as a "pharmaceutical composition." The specification does not adequately describe or give sufficient guidance by which the instant expression vector could be used as a pharmaceutical composition because an expression vector

pharmaceutical composition is used in gene therapy as a pharmaceutical to treat a disease for therapeutic purposes, and the standard for enablement for gene therapy pharmaceutical compositions is quite higher than the standard for enablement to produce the receptor protein because while producing a protein recombinantly is routine for those of ordinary skill in the art (physicians and scientists), successful gene therapy to treat disease is not currently routine in the scientific and medical communities. An enabled expression vector for gene therapy has to provide some description or guidance as to how the difficulties of sufficient expression of the receptor protein in an *in vivo* environment would be achieved, and how to maintain that expression over time. Evidence needs to be presented as to what specific expression vector constructs could be used to transfect the appropriate target cells or tissues *in vivo* in order to treat a specific disease. A showing would have to be made that established the instant invention as being somehow involved in the pathologies or etiologies of the disorders alleged to be treatable by the instant invention. For example, many NPY receptors have been discovered in the prior art; however, the Examiner is unaware of any commercial pharmaceuticals that treat any known disease that act on any of these receptors. And there are absolutely no expression vectors employing encoded NPY receptors (or, for that matter, any other encoded G-protein coupled receptor) that are being used in gene therapy as pharmaceuticals. Since the use of gene therapy for transfecting G-protein coupled receptors for therapy is not routine or predictable, given that this receptor superfamily is comprised of seven transmembrane regions that must traverse repeatedly across the cell membrane in order to be functional (as opposed to a single

extracellular region that can be excised and used as a therapeutic soluble receptor), and because the instant specification provides no working examples to compensate for the lack of teachings in the prior art despite the high skill level of the potential practitioners, a "pharmaceutical composition" comprising the instant invention is not enabled. Deleting the word "pharmaceutical" from before "composition" in the claims would obviate the grounds of this rejection.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Valenzuela et al. (WO 00/11015, "Valenzuela"). SEQ ID NOs: 25 and 26 of Valenzuela are identical to instant SEQ ID NOs: 1 and 2, respectively, of the instant invention. See pages 40-43 and 144-145 of Valenzuela.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is ~~(703) 308-6571~~ 571-272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on ~~(703) 308-4623~~ 571 272-0887. The fax phone number for

571 272-1600

this Group is currently ~~(703) 308-4242~~, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

2/23/04

Robert C. Hayes
Patt Sig.
1600